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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,842	08/22/2006	Wilfried Braje	0480/020908	4358

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
07/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,842	BRAJE ET AL.	
	Examiner	Art Unit	
	EMILY BERNHARDT	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of applicants' response filed on 4/20/10 the following still applies.

Claim 35 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim has been expanded to include even more uses and yet applicants have still not stated for the record what type of interaction the species of claim 33 exerts at the D3 receptor. The Joyce article clearly states in the Abstract section that D3 agonists are effective for the treatment of PD. So does Dooley cited by applicants and Scwartz teaches D3 antagonists for schizophrenia. Thus one of these two uses would be considered enabled once applicants states the mechanism of action for instant species. Remaining disorders/disturbances are not enabled for the following reasons. With regard to depression mentioned briefly in the Joyce article pointed out by applicants on p.251, while depression may be a symptom of Parkinson's it does not follow that it is treatable solely or predominately by way of the D3 pathway. In fact PPX which is mentioned as having "antidepressant effects" is known also as pramipexole which is a known D2 agonist. Of the 4 newly cited references actually provided only two have been published prior to applicants' 371 filing date. Rogoz which published in 2003 is directed to anxiety. However testing done on D3 agonists employed animal models and yet results are considered only preliminary. Note concluding sentence in Abstract- "...however, further studies are necessary to elucidate the mechanism of these actions."

Laszy which published in 2005 while dealing with cognitive deficits in psychotic

patients emphasize the need for further evidence. In Laszy on p.568, left column, first paragraph the possibility of other neurotransmitters being responsible is discussed and thus the need for testing with selective D3 compounds as well as using other experimental models. Additionally, Laszy deals with only a small portion of what constitutes "cognitive disturbances". Defects such as mental retardation, all forms of dementias (eg. Pick's Disease, multi-infarct, drug-induced), all types of learning disabilities (dyslexia, autism, etc.) and amnestic syndromes are all additional examples of what constitutes cognitive disorders for which no evidence of clinical efficacy is seen. Heidbreder, a later published reference, is directed to preliminary study implicating D3 receptors for the treatment of drug addiction. The abstract mentions the possibility of other neurotransmitters being responsible so the need for selective D3 compounds in animal testing is warranted. The article deals with testing for such compounds in recognized animal models but there is no discussion of clinical success in man. While preliminary findings for SB-277011-A are encouraging, it has not been demonstrated that the drug is useful for all types of addiction which is covered by the claim language. On p.93 is a discussion for other selective D3 antagonists which exhibit inhibition for cocaine-seeking behavior- again reliance is on animal models although such findings are only considered a hypothesis for using D3 antagonists for cocaine abuse. See 2nd full paragraph, right column on p.93. Additionally, there are many types of addiction including those mentioned and tested in Heidbreder such as food, video games, internet, sex, shopping and gambling to name a few. For kidney disorders, Muhlbauer is relied on. This article appears to be a very preliminary finding as it states on p.220:

"Only few data have previously been available on the renal and systemic effects of pharmacological D3 receptor activation…". Reports on one lead compound, namely 7-OH-DPAT, suggests its use in "some forms of hypertension". Benoit relied on for an "eating disturbance" is also not seen to be compelling for even one eating disorder of which there are many including diametric opposites- eating too much or too little. The fact that the D3 receptor may be implicated in inhibition of adiposity signals as discussed on p.52 does not provide conclusive evidence of any possible treatment for any one eating disorder. Note concluding remarks in the article which stresses further research is necessary.

As stated in MPEP 2164.05(a): "The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. > Chiron Corp. v.Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application").< Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. Note Genentech vs. Novo Nordisk 42 USPQ 2d 1001 especially left column at p.1005 which states the following: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.". In the same decision at p.1004 it is clearly stated that "to be enabling the specification must teach ... how to make and use the full scope of the claimed invention without undue experimentation.". This is not the case herein.

Claims 33-35 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 22 of U.S. Patent No. 7,320,979 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species embraced herein is also embraced by the claims in the US patent which describes the same species as example 1 in the specification . Applicants' do not timely traverse this rejection nor have they expressly stated their intent to file a terminal disclaimer.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-

272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/
Primary Examiner, Art Unit 1624